

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	Billiar et al.	Art Unit	1618
Serial No.	10/676,280	Examiner	Blessing M. Fubara
Filed	September 30, 2003	Conf. No.	7071
Title	TREATMENT FOR HEMORRHAGIC SHOCK		

Commissioner for Patents
P.O. Box 1450
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DECLARATION OF DR. BRIAN S. ZUCKERBRAUN UNDER 37 CFR § 1.132


I, Brian S. Zuckerbraun, M.D., hereby declare as follows:

1. I am a co-inventor with Timothy Billiar, Augustine M. K. Choi, Carol A. McCloskey, and Leo E. Otterbein of the subject matter described and presently claimed in the above-identified application.
2. I am a physician and the Samuel P. Harbison Assistant Professor of Surgery at the University of Pittsburgh. My curriculum vitae is attached.
3. In this declaration, I intend to describe some of the differences between ischemia and hemorrhagic shock, which are two distinct medical conditions.
4. Ischemia/reperfusion is a process in which there is decreased blood flow marked by decreased delivery of oxygen and nutrients to an organ that results in a series of intracellular responses, followed by the re-establishment of blood flow, which results in an oxidative type of injury. Clinically, ischemia/reperfusion injury is usually isolated to a single organ or limb. Depending on the severity, the injury can result in failure of function of that individual organ.
5. Shock is a condition in which the metabolic needs of the organism are not met at the cellular level, resulting in consequences for the whole body. Shock influences the entire organism, both immediately and throughout the entire process. Hemorrhagic shock is a type of shock that occurs in response to bleeding. In hemorrhagic shock, blood loss results in decreased

tissue perfusion throughout the entire body and all of the organ systems. Although tissue ischemia is one component of hemorrhagic shock, the physiology and responses that occur as a result of bleeding are distinct and define the process of hemorrhagic shock. Hemorrhagic shock influences all organ systems in both individual and interdependent fashions, and is a distinct condition from ischemia.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: January 8, 2009


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